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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,765	02/04/2004	Thomas Ryan	GYN-5011	3673

27777 7590 01/23/2007
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EXAMINER

TOY, ALEX B

ART UNIT.	PAPER NUMBER
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3739

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/771,765

Applicant(s)

RYAN, THOMAS

Examiner

Alex B. Toy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 4,8,11,16 and 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9,10,12-15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on November 14, 2006. It is noted that in the Remarks, applicant's column and line numbers referring to Stern incorrectly correspond to U.S. Pat. No. 5,443,470 instead of U.S. Pat. No. 6,041,260 as cited in the previous Office Action.

Response to Arguments

Applicant's arguments with respect to the Stern ('260) rejections under 102(b) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. Upon further consideration, however, new grounds of rejection are made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards (U.S. PGPub 2001/0034518 A1).

Regarding claim 1, Edwards discloses a device for ablating a body cavity comprising:

an introducer 18 having a distal end and a proximal end and at least one channel 19, 26 therethrough (Figs. 2e and 7);

a distendable bladder 25 coupled to the distal end and being distendable within the body cavity from a substantially deflated state to an inflated state wherein it approximates an interior of at least a portion of said body cavity that is to be ablated (Fig. 6);

an inflation device coupled to the proximal end and in fluid communication with the at least one channel and with an interior of the distendable bladder, wherein activation of the inflation device causes an inflation medium to flow through the at least one channel and into the distendable bladder to thereby inflate the distendable bladder (pg. 5, ¶ 62 and Fig. 2a); and

at least one flexible resistive heating element 22, 25''' coupled to the distendable bladder, the resistive heating element being electrically coupleable to a voltage source so as to form a closed circuit in the absence of direct or indirect contact with any body fluid or tissue, and emitting resistive heat through the flexible resistive heating element when so coupled, the resistive element being coupled to the distendable bladder in a manner so as not to impair movement of the bladder from the deflated to the inflated states (pg. 4, ¶ 56, 58 and Figs. 2e and 7).

Regarding claims 2 and 3, Edwards further discloses the device, wherein the at least one resistive heating element 25''' is coupled to an inner 25'' or outer 25' surface of the distendable bladder 25 (pg. 4, ¶ 58 and Figs. 2e).

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Regarding claims 5-7, Edwards discloses the device, wherein one or a plurality of flexible resistive heating elements 22 is coupled to the distendable bladder 25 along a serpentine path so as to cover a predetermined portion(s) of a surface area of the bladder (Figs. 7 and 8).

Regarding claims 12-14, Edwards further discloses the device, wherein the inflation medium is a fluid, gas, or air (pg. 5, ¶ 62).

Regarding claim 15, see the preceding rejection of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-7, 9-10, 12-15, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern (U.S. Pat. No. 6,041,260) in view of Edwards (U.S. PGPub 2001/0034518 A1).

Regarding claim 1, Stern discloses a device for ablating a body cavity comprising:

an introducer 16 having a distal end and a proximal end and at least one channel 18 therethrough (Figs. 1-2);

a distendable bladder 14 coupled to the distal end and being distendable within the body cavity from a substantially deflated state to an inflated state wherein it approximates an interior of at least a portion of said body cavity that is to be ablated (col. 4, ln. 34-38 and Figs. 1-2);

an inflation device coupled to the proximal end and in fluid communication with the at least one channel and with an interior of the distendable bladder, wherein activation of the inflation device causes an inflation medium to flow through the at least one channel and into the distendable bladder to thereby inflate the distendable bladder (col. 4, ln. 34-38, col. 7, ln. 7-9, and Figs. 1 and 10a); and

at least one flexible resistive heating element 40 coupled to the distendable bladder (col. 2, ln. 1-9, col. 5, ln. 38-44, and Fig. 4a), the resistive heating element being electrically coupleable to a voltage source and emitting resistive heat when so coupled (col. 5, ln. 44-48 and Abstract), the resistive element being coupled to the distendable bladder in a manner so as not to impair movement of the bladder from the deflated to the inflated states (col. 5, ln. 41-44 and Fig. 4a).

Since the resistive elements 40 on the balloon are segmented and Stern clearly discloses that the balloon is designed to inflate and deflate, the resistive elements are inherently coupled to the distendable bladder in a manner so as not to impair movement

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of the bladder from the deflated to the inflated states. In addition, resistive elements must be inherently flexible since they allow the balloon to expand and conform to the expanded balloon surface.

The claim differs from Stern in calling for the flexible resistive heating element to be coupled to a voltage source so as to form a closed circuit in the absence of direct or indirect contact with any body fluid or tissue, and emit resistive heat through the flexible resistive heating element when so coupled.

Edwards, however, teaches an analogous device for ablating a body cavity comprising a distendable bladder, an inflation device, and at least one flexible resistive heating element 22, 25''' as claimed (pg. 4, ¶ 56, 58 and Fig. 2e). Edwards further teaches that the flexible resistive element is an obvious alternate type of heat delivery device that is an interchangeable equivalent to an RF electrode (pg. 4, ¶ 56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a resistive heating element as claimed in the device of Stern in view of the teaching of Edwards as an obvious alternate type of heat delivery device that is an interchangeable equivalent to an RF electrode.

Regarding claims 2 and 3, Stern further discloses the device, wherein the at least one resistive heating element is coupled to an inner or outer surface of the distendable bladder (col. 5, ln. 38-44).

Regarding claims 5-7 and 10, Stern further discloses the device, wherein one or a plurality of flexible resistive heating elements 170, 172 is coupled to the distendable bladder along a serpentine path so as to cover a predetermined portion(s) of a surface

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area of the bladder (col. 6, ln. 59-65 and Fig. 9), and wherein when the distendable bladder is in the inflated state, the first and second resistive heating elements are in thermal contact with first and second portions of the endometrial lining of the uterus (Fig. 1).

Regarding claim 9, Stern further discloses the device, wherein the body cavity is the uterus, and wherein, when in the inflated state, the distendable bladder approximates an interior of the uterus (col. 4, ln. 34-38 and Fig. 1).

Regarding claims 12-14, Stern further discloses the device, wherein the inflation medium is a fluid, gas, or air (col. 4, ln. 34-38).

Regarding claim 15, see the preceding rejection of claim 1.

Regarding claim 17, see the preceding rejection of claims 9 and 15.

Regarding claims 18 and 19, see the preceding rejection of claim 15 and Fig. 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

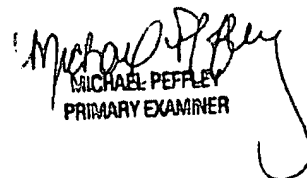
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT

1/17/07


MICHAEL PEFFLEY
PRIMARY EXAMINER